

### **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 3/10/10 has been entered.

### ***Information Disclosure Statement***

The information disclosure statement (IDS) submitted on 3/10/10 was filed after the mailing date of the Notice of Allowance on 12/08/09. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant

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regards as the invention. Claim 5 recites “warm air” . Warm is a relative term. With nothing to compare to in order to gauge the metes and bounds of what is meant by warm the claim is indefinite. Warm could be with respect to body temperature or it could be with respect to air temperature. The claim will be examined as it reads on any air.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 6-8 are rejected under 35 U.S.C. 102(b) as being anticipated by the DERWENT-ACC-NO: 1990-261596 Abstract of DE 3904311.

The Abstract discloses volatile essential oils (which inherently have flavor) encapsulated in a polymer film to form capsules that are applied to a substrate that comprises a polymer film. It is the Examiner’s position that the film inherently has at least one surface disposed thereon an encapsulated substance and that the film is dissolvable in, for example, aqua regia or some organic solvent, in the absence of evidence to the contrary.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 6 and 9 rejected under 35 U.S.C. 102(b) as being anticipated by Marx (US 5651982).

Marx discloses a composition comprising a fibrin glue film and liposomes containing active ingredients such as polysaccharides which is starch (claims 1, 2, 8, 9, 15, 18, 19, and 28). Liposomes encapsulate the active. It is the Examiner's position that the film inherently has at least one surface disposed thereon an encapsulated substance and that the film is dissolvable in, for example, aqua regia or some other solvent, in the absence of evidence to the contrary.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maxwell et al. (US 20040253191) and Gilleland et al. (US 6375981) and Kulkarni et al. (US 2003/0211136).

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Applicant claims methods of making a dissolvable film with an encapsulated substance, the product and a method of preserving a flavor of an active.

#### **Determination of the scope and content of the prior art**

**(MPEP 2141.01)**

Maxwell et al. teaches an edible film composition comprising a film forming agent comprising maltodextrin, a filler, such as cellulose or a cellulose polymer, and a hydrocolloid such as gelatin, biosynthetic process starch and a cellulosic material and a combination of essential oils, such as spearmint, which intrinsically have a flavor (Abstract; [0060-0075] and claims 1-13). In addition, flavoring agents are added such as essential oils such as mint, spearmint, menthol, eucalyptol, and thymol (claims 34 and 37-39).

Maxwell et al. teach methods of making the film in [0078-0080] and claim 62:

**62. A method of making a Pullulan-free film comprising:**

- a.) forming an aqueous solution that includes a maltodextrin, a hydrocolloid, and a filler;
- b.) adding an effective amount of an antimicrobial agent to the aqueous solution, wherein the antimicrobial agent comprises a combination of essential oils selected from the group of pairs consisting of cinnamic aldehyde & salicylaldehyde, cinnamic aldehyde & citral, salicylaldehyde & citral, cinnamic aldehyde & peppermint oil, cinnamic aldehyde & spearmint oil, salicylaldehyde & peppermint oil, salicylaldehyde & spearmint oil and, citral & spearmint oil and;
- c.) drying the aqueous solution to form a dry edible film.

Maxwell et al. teach encapsulation of the essential oils ([0028] and claim 78).

Maxwell et al. teach films with water from 10-11% by weight (Table 3, examples 11-15) and examples without water (Table 4, examples 16-20 and Table 5, examples 21-25) which the Examiner interprets to read on about 10 weight % or less moisture.

Gilleland et al. teach using hydroxyalkyl and succinate starch in edible films (abstract and claims 1-6).

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Kulkarni et al. teach fast dissolving orally consumable films containing a water soluble polymer such as pullulan or hydroxypropylated high amylose starch, and essential oils such as thymol, menthol, methyl salicylate and eucalyptol in a single layer film that are made by drying with warm air (abstract; [0136]; and claims 1-24).

### **Ascertainment of the difference between the prior art and the claims**

#### **(MPEP 2141.02)**

1. The difference between the instant application and Maxwell et al. is that Maxwell et al. do not expressly teach a dissolvable film with encapsulated substance with modified starch that is hydroxyalkylated starch or succinated starch or method of making the dissolvable film with encapsulated substance wherein the encapsulant is water soluble and disposed on at least one surface and wherein the drying is with air or warm air. This deficiency in Maxwell et al. is cured by common sense and the teachings of Gilleland et al. and Kulkarni et al.

2. The difference between the instant application and Maxwell et al. is that Maxwell et al. do not expressly teach a method of preserving the flavor of an active to be delivered by a film or placing the encapsulated active on the film after film forming but prior to drying.

### **Finding of prima facie obviousness**

#### **Rational and Motivation (MPEP 2142-2143)**

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1. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to make a dissolvable film with encapsulated substance with modified starch that is hydroxyalkylated starch or succinated starch or method of making the dissolvable film with encapsulated substance comprising coating a substrate and wherein the encapsulant is water soluble and dried by air/warm air, as suggested by Kulkarni et al. and Gilleland et al., and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Maxwell et al. teach encapsulating the essential oil and it is no stretch of the imagination to add the encapsulated oil to the film of Maxwell et al. While Maxwell et al. do not expressly teach coating a substrate to form the film, such is understood by the artisan as the film is not made in zero gravity and must be on something. Furthermore, air drying with warm air that is suitable for drying is not only obvious given the teachings of Maxwell et al. in [0079-0080]:

solution then can be dried in any suitable manner, thereby, forming the edible film.

[0080] It should be appreciated that any suitable type, number and arrangement of process procedures or steps (i.e. mixing, heating, drying, cooling, addition of ingredients), process parameters (i.e. temperature, pressure, pH, process times) or the like can be utilized.

but also warm air drying of films is taught by Kulkarni et al.

With regard to adding the modified starch, the art already teaches the use of these starches in edible films and therefore it is: "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same

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purpose, in order to form a third composition to be used for the very same purpose....

[T]he idea of combining them flows logically from their having been individually taught in the prior art.” *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

With regard to the encapsulant being water soluble, such is obvious to one of ordinary skill in the art because the essential oil is to be released in the oral cavity and hence any encapsulating material must dissolve under the conditions of the oral cavity to release its contents. Furthermore, the encapsulated substance is intrinsically disposed on at least one surface in the absence of evidence to the contrary. This is after all, simply a film and not a capsule or tablet.

2. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to use the method of Maxwell et al. for a method of preserving the flavor of an active to be delivered by a film or placing the encapsulated active on the film after film forming but prior to drying and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because: 1) the method is intrinsic to the method of Maxwell et al.; and 2) with regard to the order of the process steps: MPEP 2144.03 IV: “See also *In re Burhans*, 154 F.2d 690, 69 USPQ 330 (CCPA 1946) (selection of any order of performing process steps is prima facie obvious in the absence of new or unexpected results); *In re Gibson*, 39 F.2d 975, 5 USPQ 230 (CCPA 1930) (Selection of any order of mixing ingredients is prima facie obvious.).”



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In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leung et al. (WO 00/018365) in view of Boskovic et al. (US 5124162) and Kulkarni et al. (US 2003/0211136).

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Applicant claims methods of making a dissolvable film with an encapsulated substance and a method of preserving the flavor of an active.

### **Determination of the scope and content of the prior art**

#### **(MPEP 2141.01)**

Leung et al. teach fast dissolving orally consumable films comprising pullulan and **essential oils** such as thymol, methyl salicylate, eucalyptol and menthol (abstract and claims 1-47). Leung et al. teach methods of making the films comprising mixing the ingredients, casting on a substrate and drying (page 41, lines 1-22 and claims 18-27, 29

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and 30). The method makes a product that has water content is less than 10% (claim 17). Hydroxyalkyl modified starches (hydroxyethyl cellulose, for example) are used (claim 7).

Boskovic et al. teach encapsulation of essential oils with carbohydrate films that are stable against oxidation (Abstract; column 5, lines 38-40; column 6, lines 30-38; and claims 1-19).

Kulkarni et al. teach fast dissolving orally consumable films containing a water soluble polymer such as pullulan or hydroxypropylated high amylose starch, and essential oils such as thymol, menthol, methyl salicylate and eucalyptol in a single layer film that are made by drying with warm air (abstract; [0136]; and claims 1-24).

#### **Ascertainment of the difference between the prior art and the claims**

##### **(MPEP 2141.02)**

1. The difference between the instant application and Leung et al. is that Leung et al. do not expressly teach a method that an encapsulated substance or involves air or warm air drying. This deficiency in Leung et al. is cured by the teachings of Boskovic et al. and Kulkarni et al. and common sense.

2. The difference between the instant application and Leung et al. is that Leung et al. do not expressly teach a method of preserving the flavor of an active to be delivered by a film or placing the encapsulated active on the film after film forming but prior to drying.

#### **Finding of prima facie obviousness**

**Rational and Motivation (MPEP 2142-2143)**

1. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to use the encapsulated essential oils, as suggested by Boskovic et al., in the method of Leung et al. and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Boskovic et al. teach that encapsulation makes the composition stable against oxidation which is an important consideration on the shelf life of a consumable product. Therefore, one of ordinary skill in the art would have used encapsulated essential oils in the method of Leung et al. to make a film with encapsulated substance disposed on at least one surface.

Leung et al. teach drying the material and Kulkarni et al. teach using warm air to dry these types of films and thus it is obvious to use warm air to do so.

2. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to use the method of Leung et al. for a method of preserving the flavor of an active to be delivered by a film or placing the encapsulated active on the film after film forming but prior to drying and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because: 1) the method is intrinsic to the method of Leung et al.; and 2) with regard to the order of the process steps: MPEP 2144.03 IV: "See also *In re Burhans*, 154 F.2d 690, 69 USPQ 330 (CCPA 1946) (selection of any order of performing process steps is prima facie obvious in the absence of new or unexpected results); *In re Gibson*, 39 F.2d 975, 5 USPQ 230 (CCPA 1930) (Selection of any order of mixing ingredients is prima facie

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obvious.).”

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

### ***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ernst V. Arnold whose telephone number is 571-272-8509. The examiner can normally be reached on M-F (7:15 am-4:45 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Ernst V Arnold/  
Primary Examiner, Art Unit 1616